

STATISTICAL BRIEF

ORGAN TRANSPLANT SERVICES

This statistical brief is one of a series designed to provide data annually for monitoring the availability and utilization of certain health care resources in compliance with the Commission's State Health Plan for Facilities and Services. Under COMAR 10.24.15.04C, existing providers of organ transplant services in Maryland are to operate at or above minimum volumes, comply with the requirements of certification and/or accreditation, and report outcome data. This brief includes the most recent annual data available from the specified sources.

Organ transplant services include the transplantation of organs or tissues, including transplantable cells. To plan for transplant services, MHCC has established two regional service areas. The Maryland region provides service to residents of Maryland, excluding Charles, Montgomery, and Prince George's counties; the Washington region serves those counties, plus Washington, D.C. and Northern Virginia. The Maryland Certificate of Need Program regulates non-federal hospitals in Maryland.

Based on evidence that the volume of organ transplant procedures correlates with outcomes such as survival rates, the Commission has established minimum volume requirements for each program type. Threshold volumes, generally higher than minimum, are a guide for measuring adverse impact on existing programs when the Commission considers the development of additional capacity.

Solid Organ Transplantation

The major solid organs include kidney, liver, pancreas, heart, and lung. National data include intestine transplants (80 in 2000; 108 in 2002). No minimum volume has been established for intestine transplants.

The number of registrations on the national waiting list for organ transplants continues to exceed the supply of donated organs. From 2000 to 2002, there was a 5 percent average yearly increase in the waiting list (79,346 to 86,623), and a 4 percent average yearly increase in transplants occurring (22,897 to 24,847).

The number of organ donors has been steadily increasing, an average of 4 percent per year from 2000 to 2002 (11,809 to 12,803). One reason for this increase is the impact in recent years of the greater use of living donors, which has increased at an average of 7 percent per year from 2000 to 2002 (5,823 to 6,621).

Hospitals within the Maryland region currently performing solid organ transplants are Johns Hopkins Hospital (JHH) and the University of Maryland Medical Center (UMMC). Transplant services are also available to Maryland residents at hospitals within the Washington region: Children's National Medical Center (Children's), Georgetown University Medical Center (GUMC), Howard University Hospital (HUH), Washington Hospital Center (WHC), and Inova Fairfax Hospital (Fairfax). In addition, the region includes programs at one federal hospital, Walter Reed Army Medical Center (WRAMC).

The number of transplants occurring in the Maryland and Washington regions over the most recent three years has

declined. After peaking in 2000 (1,168 procedures), transplants declined an average of 5 percent per year from 2000 to 2002.

Data available show that the number of organ donors in the Maryland and Washington regions has shown a similar decline (6 percent per year) over the same period. Living donors decreased 9 percent per year (435 to 358), while deceased donors increased 1 percent per year (165 to 169). In 2001, the average deceased donor provided 3.6 organs.

Utilization at Maryland and Washington Regional Transplant Centers by Organ Type: 2000 – 2002.

| Organ | Minimum Volume | Facility | 2000 | 2001 | 2002 |
|-----------------|---|-------------|------|------|------|
| Kidney | 30 | JHH* | 161 | 164 | 176 |
| | | UMMC* | 413 | 384 | 252 |
| | | GUMC* | 46 | 38 | 47 |
| | | HUH* | 5 | 4 | 6 |
| | | WHC* | 99 | 100 | 97 |
| | | Fairfax* | 85 | 94 | 102 |
| | | Children's* | 8 | 12 | 8 |
| Pancreas | 12 | WRAMC | 33 | 38 | 39 |
| | | JHH | 6 | 2 | 4 |
| | | UMMC | 49 | 47 | 35 |
| | | GUMC | 0 | 0 | 1 |
| | | WHC | 1 | 4 | 4 |
| | | Fairfax | 0 | 2 | 6 |
| Kidney-Pancreas | There is no minimum volume. Counts may be included in respective organ program. | WRAMC | 0 | 0 | 1 |
| | | JHH | 3 | 3 | 2 |
| | | UMMC | 19 | 11 | 6 |
| | | GUMC | 1 | 1 | 3 |
| | | HUH | 0 | 1 | 0 |
| | | WHC | 8 | 9 | 9 |
| | | Fairfax | 5 | 6 | 4 |
| Liver | 12 | WRAMC | 3 | 2 | 0 |
| | | JHH* | 48 | 50 | 48 |
| | | UMMC* | 32 | 28 | 25 |
| | | GUMC* | 37 | 46 | 51 |
| Heart | 12 | Fairfax* | 19 | 24 | 18 |
| | | JHH* | 21 | 21 | 19 |
| | | UMMC | 2 | 0 | 13 |
| | | WHC* | 7 | 5 | 5 |
| | | Children's | 1 | 0 | 0 |
| Lung | 12 | Fairfax* | 10 | 12 | 15 |
| | | JHH* | 19 | 19 | 25 |
| | | UMMC* | 6 | 3 | 6 |
| | | Fairfax* | 19 | 23 | 21 |
| Heart-Lung | 12 Count may include heart or lung transplants. | JHH* | 2 | 0 | 0 |
| | | UMMC | 0 | 0 | 0 |
| | | Fairfax* | 0 | 0 | 0 |

Source: UNOS OPTN Data as of March 14, 2003.

* Medicare-Approved Transplant Programs, as of April 2003, for Heart and Lung programs; October 2002, for Kidney; and July 2002, for Liver programs.

Medicare does not approve facilities to perform pancreas transplantation. Medicare will cover pancreas transplantation when it is performed simultaneous with or after a kidney transplant, based on the provisions of Section 35-82 of the Medicare Coverage Issues Manual.

As of April 24, 2003, all transplant programs operating in Maryland, Washington, D.C., and Northern Virginia were certified by the United Network for Organ Sharing (UNOS), which administers the Organ Procurement and Transplantation Network (OPTN).

The primary outcome data for transplantation are survival rates. Survival rate statistics for center-specific outcomes by solid organ type for aggregated years can be found at <http://www.ustransplant.org/center-adv.html>. The data found on the website of the Scientific Registry of Transplant Recipients is regularly updated with the most recent data available.

Stem Cell Transplantation

There are two major types of hematopoietic stem cell transplantation, autologous and allogeneic, which are categorized based on donor types. Currently, the SHP states that stem cell transplant programs should be affiliated with a teaching hospital, and allogeneic stem cell transplantation should be limited to academic medical centers only.

Hospitals within the Maryland region currently performing stem cell transplants are JHH and UMMC. The Washington region includes Holy Cross Hospital (HCH) in Maryland, plus a number of hospitals within Washington, D.C. and Northern Virginia that provide transplant services to Maryland residents. In addition, WRAMC performs autologous transplant procedures.

Utilization of autologous stem cell transplants in the Maryland and Washington regions has stabilized over the past three years, after the large drop in volumes in 1999 and 2000. However, volumes fell below minimum requirements at some facilities.

Utilization at Maryland and Washington Regional Transplant Centers by Stem Cell Type: 2000 – 2002.

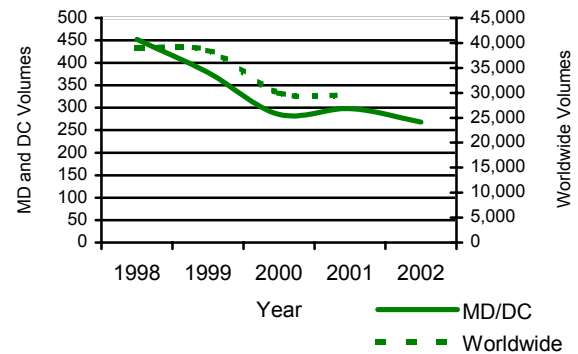
| Cell Type | Minimum Volume | | 2000 | 2001 | 2002 |
|------------|----------------|-------------|------|------|------|
| Autologous | 10 | HCH† | 4 | 0 | 0 |
| | | GBMC†* | 11 | 2 | 2 |
| | | JHH† | 88 | 108 | 81 |
| | | Sinai* | 8 | 1 | 7 |
| | | UMMC† | 74 | 61 | 64 |
| | | Children's† | 7 | 5 | 20 |
| | | GUMC† | 5 | 27 | 32 |
| | | WHC* | 11 | 0 | - |
| | | GWUH | 12 | 4 | 0 |
| | | Fairfax† | 41 | 40 | 24 |
| Allogeneic | 10 | WRAMC† | 24 | 50 | 38 |
| | | JHH† | 78 | 83 | 81 |
| | | UMMC† | 20 | 22 | 29 |
| | | Children's† | 13 | 11 | 9 |
| | | GUMC† | 3 | 24 | 16 |
| | | GWUH | 4 | 1 | 0 |
| | | Fairfax† | 4 | 5 | 5 |

Source: MHCC Quarterly Survey

†Accredited by the Foundation for the Accreditation of Cellular Therapy (FACT)

* Sinai Hospital, as of July 24, 2002, accepted no new transplant patients and performed its last procedure on August 27, 2002; WHC closed its program, effective March 31, 2001; on April 17, 2003, GBMC notified the Commission that it decided to close its program.

Autologous Transplantation Volumes in the Maryland and Washington Regions and Worldwide: 1998-2002



Sources: MD/DC data - MHCC Quarterly Survey, Worldwide - IBMTR/ABMTR

In the past two years, several autologous programs have consolidated or closed due to the decreasing volumes. The Washington Hospital Center consolidated its autologous stem cell transplant program with Georgetown University Medical Center, effective March 31, 2001. Due to low volumes, Sinai Hospital, as of July 24, 2002, accepted no new transplant patients and performed its last procedure on August 27, 2002. On April 17, 2003, the Cancer Center at Greater Baltimore Medical Center notified the Commission that the hospital decided to close its autologous bone marrow transplant program due to low accruals.

The Commission works with transplant programs to identify the reasons for consistently low volumes. The decline in autologous stem cell transplantation volumes has been attributed to the revelation of fraud in the research that had indicated high-dose chemotherapy with autologous transplantation as an effective treatment for breast cancer. This trend has been seen nationally and internationally.

Some community-based programs also reported low referrals from insurance companies limiting coverage and access to selected facilities. Insurers often use additional requirements in establishing networks of transplant centers to serve their members.

Currently, the clinical indications for stem cell transplantation are relatively rare diseases. New indications for autologous transplant treatment, such as autoimmune diseases, are emerging; however, volumes of autologous transplantation are likely to remain static over the next three years.

Limited survival statistics can be found at http://www.marrow.org/PATIENT/understanding_survival_statistics.html for Johns Hopkins Hospital, University of Maryland Medical Center, and other facilities participating in the National Marrow Donor Program (NMDP).